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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,042	05/02/2006	Shigeyoshi Nishino	740709-546	1891
22204 7590 04/27/2009 NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128				
EXAMINER MOORE, SUSANNA				
ART UNIT		PAPER NUMBER		
1624				
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04/27/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/561,042

**Applicant(s)**

NISHINO ET AL.

**Examiner**

SUSANNA MOORE

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 6 and 13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) 1, 3, 4, 6 and 13 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **Prosecution has been reopened.**

Applicant's arguments, see Remarks, filed 4/3/2009, with respect to Office Action mailed 12/3/2008 have been fully considered. Some of the rejections have been withdrawn, others have been maintained, and some are new rejections or are new as a result of Applicant's amendments. Thus, this is a second Final Office Action. In summary, claims 1, 3, 4, 6 and 13 are currently pending and under consideration.

#### ***Specification***

The objection of the title of the invention is withdrawn based on the amendment.

#### ***Claim Objections***

The objection of claim 1, drawn to an invention nonelected without traverse in the paper of 3/17/2008 is withdrawn based on the amendment.

#### ***Claim Rejections - 35 USC § 102***

Claims 1, 3, 4, 6 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishino et. al. (WO 03/051849, US equivalent 7232903 B2) is withdrawn based on the remarks.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobe et. al. (Bioorg. Med. Chem., 2003, 11, 383-391) in view of Turner, Mayer et al., Chen et al., Science, USP 4138433, or USP 4081455.

The instant Application claims the reaction of compounds of formula (6), 2-aminobenzamides, with compounds of formula (4), trioxo formate acid derivatives (trimethylformate) and amine compounds of formula (2) in an organic solvent (polar solvent according to claim 3) with heating (range 40° C-200° C), according to claim 6, which results in the compounds of formula (7), quinazolin-4-ones.

The reference teaches the compounds of formula (7), wherein 2-aminophenyl carboxylic acid with aqueous ammonia solution (formula 2), followed by reaction with trimethylformate (formula 4) in sequential steps at room temperature and cooling, respectively. See page 385, Scheme 2 at the top of the page and page 388, in the left-hand column the third and fourth full paragraphs.

The differences between the reference and the instant Application are a) the solvents used in the reaction and b) the one sequential step versus Applicant's one pot reaction.

a) The solvent used for the reaction, which can be found in the ammonia solutions, aqueous versus Applicant's organic solvent (preferably polar organic solvent). Ammonia can be purchased at Sigma-Aldrich in ethanol, see Aldrich reference. These two solvents are alternatively useable since the reaction may proceed with either solvent present in the reaction.

b) The sole difference between the claimed process and the prior art process is that the prior art process purifies the intermediate and then proceeds to the next step, whereas applicants do the step consecutively without isolation of the intermediate. Such a variation is obvious to one of ordinary skill in the art of synthetic organic chemistry. Turner, "The Design of Organic Synthesis" (Elsevier, 1976), pages 10 and 149, says, "If several steps are necessary, 'A' to 'B' to 'C', ideally they should be carried out consecutively in the same medium, without isolation of the intermediates." (page 10) Applicants have thus just done what is known to be the preferred mode. Similarly, page 149 says, "increasingly in industry, it is attractive and advantageous to carry out more than one transformation in a pot, often by consecutive addition of reagents. The product is only isolated after two, three or more reactions." This is the same principle. A similar teaching appears in Mayer et al., Chem Soc. Rev., 30, 332 (2001). This says, "However, it would be much more efficient if several bonds could be formed in a single sequence without isolation of intermediates. It is obvious that this type of reaction would be more economic by requiring fewer reagents, solvents and absorbents and less energy and labour together with a reduction in waste." (page 332). The reference Chen et al., Angewandte Chemie Int. Ed. Volume 37, Issue 1/2, Pages 91 - 93 (1998) says, "Integration of multistep chemical reactions into one-pot

reactions is of great significance from both economical and ecological points of view. A number of one-pot processes ... are performed in sequence without isolating intermediates." The reference Science 310, page 409 (21 October 2005) says, "Multistep synthesis is more efficient when two or more reactions are run consecutively in the same flask, thereby eliminating isolation and purification steps." In USP 4138433, column 4, lines 48-55 state, "It is to be considered a special advantage of the process according to the invention, that the so-called "one-vessel-reaction" (= reaction without isolation of intermediate products) does away with cumbersome processing steps such as isolation and purification of an intermediate product so that the overall reaction period may be cut down substantially." In USP 4081455, column 11, lines 5-19 state, "In addition to the step-wise reactions in Reaction Scheme I, it is possible, and frequently advantageous, to conduct various of the steps in a "one-pot" process without isolation of the intermediates ... These "one-pot" processes eliminate the need to isolate and/or purify intermediates, are more convenient, simple, and economical to run, and frequently afford improved yields over those realized by proceeding in step-wise fashion." Many more references could be provided, as this is an expedient well known to be desirable. Accordingly, such a variation is obvious; one would be motivated to do this to obtain the advantages which are well known to arise from not isolating or purifying an intermediate.

Thus, said claims are rendered obvious by Tobe et al.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/  
Examiner, Art Unit 1624

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624